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Patent Application
of
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for

DISEASE SIMULATION SYSTEM AND METHOD

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation copending patent application 08/781,278 filed January 10, 1997, which is herein incorporated by reference.

BACKGROUND -- FIELD OF THE INVENTION

The present invention relates generally to disease simulation systems, and in particular to a system and method for simulating a disease control parameter and for predicting the effect of patient self-care actions on the disease control parameter.

BACKGROUND -- DESCRIPTION OF PRIOR ART

Managing a chronic disease or ongoing health condition requires the monitoring and controlling of a physical or mental parameter of the disease. Examples of these disease control parameters include blood glucose in diabetes, respiratory flow in asthma, blood pressure in hypertension, cholesterol in cardiovascular disease, weight in eating disorders, T-cell or viral count in HIV, and frequency or timing of episodes in mental health disorders. Because of

the continuous nature of these diseases, their corresponding control parameters must be monitored and controlled on a regular basis by the patients themselves outside of a medical clinic.

Typically, the patients monitor and control these parameters in clinician assisted self-care or outpatient treatment programs. In these treatment programs, patients are responsible for performing self-care actions which impact the control parameter. Patients are also responsible for measuring the control parameter to determine the success of the self-care actions and the need for further adjustments. The successful implementation of such a treatment program requires a high degree of motivation, training, and understanding on the part of the patients to select and perform the appropriate self-care actions.

One method of training patients involves demonstrating the effect of various self-care actions on the disease control parameter through computerized simulations. Several computer simulation programs have been developed specifically for diabetes patients. Examples of such simulation programs include *BG Pilot* ™ commercially available from Raya Systems, Inc. of 2570 El Camino Real, Suite 520, Mountain View, CA. 94040 and *AIDA* freely available on the World Wide Web at the Diabetes UK website http://www.pcug.co.uk/diabetes/aida.htm.

Both *BG Pilot* ™ and *AIDA* use mathematical compartmental models of metabolism to attempt to mimic various processes of a patient's physiology. For example, insulin absorption through a patient's fatty tissue into the patient's blood is represented as a flow through several compartments with each compartment having a different flow constant. Food absorption from mouth to stomach and gut is modeled in a similar manner. Each mathematical compartmental model uses

partial differential equations and calculus to simulate a physiological process.

This compartmental modeling approach to disease simulation has several disadvantages. First, understanding the compartmental models requires advanced mathematical knowledge of partial differential equations and calculus which is far beyond the comprehension level of a typical patient. Consequently, each model is an unfathomable "black box" to the patient who must nevertheless trust the model and rely upon it to learn critical health issues.

A second disadvantage of the compartmental modeling approach is that a new model is needed for each new disease to be simulated. Many diseases involve physiological processes for which accurate models have not been developed. Consequently, the mathematical modeling approach used in *BG Pilot* ™ and *AIDA* is not sufficiently general to extend simulations to diseases other than diabetes.

A further disadvantage of the modeling approach used in *BG Pilot* ™ and *AIDA* is that the mathematical models are not easily customized to an individual patient. As a result, *BG Pilot* ™ and *AIDA* are limited to simulating the effect of changes in insulin and diet on the blood glucose profile of a typical patient. Neither of these simulation programs may be customized to predict the effect of changes in insulin and diet on the blood glucose profile of an individual patient.

OBJECTS AND ADVANTAGES OF THE INVENTION

In view of the above, it is an object of the present invention to provide a disease simulation system which is sufficiently accurate to teach a patient appropriate self-care actions and sufficiently simple to be understood by the

average patient. It is another object of the invention to provide a disease simulation system which may be used to simulate many different types of diseases. A further object of the invention is to provide a disease simulation system which may be easily customized to an individual patient.

These and other objects and advantages will become more apparent after consideration of the ensuing description and the accompanying drawings.

SUMMARY OF THE INVENTION

The invention presents a system and method for simulating a disease control parameter and for predicting the effect of patient self-care actions on the disease control parameter. According to the method, a future disease control parameter value $X(t_j)$ at time t_j is determined from a prior disease control parameter value $X(t_i)$ at time t_i based on an optimal control parameter value $R(t_j)$ at time t_j, the difference between the prior disease control parameter value $X(t_i)$ and an optimal control parameter value $R(t_i)$ at time t_i, and a set of differentials between patient self-care parameters having patient self-care values $S_M(t_i)$ at time t_i and optimal self-care parameters having optimal self-care values $O_M(t_i)$ at time t_i. In the preferred embodiment, the differentials are multiplied by corresponding scaling factors K_M and the future disease control parameter value $X(t_j)$ is calculated according to the equation:

$$X(t_j) = R(t_j) + (X(t_i)-R(t_i)) + \sum_M K_M(S_M(t_i)-O_M(t_i)).$$

A preferred system for implementing the method includes an input device for entering the patient self-care values $S_M(t_i)$. The system also includes a memory for storing the optimal control parameter values $R(t_i)$ and $R(t_j)$, the prior disease

control parameter value $X(t_i)$, the optimal self-care values $O_M(t_i)$, and the scaling factors K_M. A processor in communication with the input device and memory calculates the future disease control parameter value $X(t_j)$. A display is connected to the processor to display the future disease control parameter value $X(t_j)$ to a patient.

In the preferred embodiment, the system further includes a recording device in communication with the processor for recording an actual control parameter value $A(t_i)$ at time t_i, an actual control parameter value $A(t_j)$ at time t_j, and actual self-care parameters having actual self-care values $C_M(t_i)$ at time t_i. The processor adjusts the scaling factors K_M based on the difference between the actual control parameter value $A(t_j)$ and the optimal control parameter value $R(t_j)$, the difference between the actual control parameter value $A(t_i)$ and the optimal control parameter value $R(t_i)$, and the difference between the actual self-care values $C_M(t_i)$ and the optimal self-care values $O_M(t_i)$. Thus, the scaling factors K_M are customized to an individual patient to predict the effect on the disease control parameter of self-care actions performed by the individual patient.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic diagram of a simulation system according to the invention.

FIG. 2 is a sample physiological parameter entry screen according to the invention.

FIG. 3 is a sample self-care parameter entry screen according to the invention.

FIG. 4 is a table of values according to the invention.

FIG. 5 is a sample graph of disease control parameter values created from the table of FIG. 4.

FIG. 6 is another table of values according to the invention.

FIG. 7 is a sample graph of disease control parameter values created from the table of FIG. 6.

FIG. 8 is another table of values according to the invention.

FIG. 9 is a sample graph of disease control parameter values created from the table of FIG. 8.

FIG. 10 is a schematic illustration of the entry of actual parameter values in a recording device of the system of FIG. 1.

FIG. 11 is a schematic diagram of another simulation system according to the invention.

FIG. 12 is a schematic block diagram illustrating the components of the system of FIG. 11.

FIG. 13 is a flow chart illustrating steps included in a method of the invention.

FIG. 14 is a flow chart illustrating steps included in another method of the invention.

DESCRIPTION

The present invention is a system and method for simulating a disease control parameter and for predicting an effect of patient self-care actions on the disease control parameter. In the following detailed description, numerous specific details are set forth in order to provide a thorough understanding of the present invention. However, it will be apparent to one of ordinary skill in the art that these specific details need not be used to practice the invention. In other instances, well known structures, interfaces, and processes are not shown in detail to avoid unnecessarily obscuring the present invention.

FIGS. 1 - 10 illustrate a preferred embodiment of a simulation system according to the invention. The following table illustrates a representative sampling of the types of diseases, patient self-care parameters, and disease control parameters which may be simulated using the system and method of the invention.

Disease	Self-Care Parameters	Control Parameter
Diabetes	insulin, diet, exercise	blood glucose level
Asthma	allergens, exercise, inhaled bronchial dilators, anti-inflammatory medications	peak flow rate
Obesity	diet, exercise, metabolism altering medications	weight
Hypertension	diet, exercise, stress reduction, blood pressure medications	blood pressure
Coronary Artery Disease	diet, exercise, stress reduction, lipid lowering medications	cholesterol
Panic Disorder	stress reduction, anti-depressant medications	number of episodes
Nicotine Addiction	cigarettes smoked, coping behaviors	urges to smoke

The above table is not intended as an exhaustive list, but merely as a representative sampling of the types of diseases and disease control parameters which may be simulated. For simplicity, the preferred embodiment is described with reference to a single disease, diabetes, having a single disease control parameter, a blood glucose level. However, it is to be understood that the system and method of the invention are sufficiently flexible to simulate any disease which has a measurable control parameter and which requires patient self-care actions.

Referring to FIG. 1, a simulation system generally indicated at **10** includes a server **12** having a processor and memory for executing a simulation program which will be described in detail below. Server **12** is in communication with a healthcare provider computer **14** through a network link **48**.

Healthcare provider computer **14** is preferably a personal computer located at a healthcare provider site, such as a doctor's office.

Server **12** is also in communication with a patient multi-media processor **24** through a network link **50**. Patient multi-media processor **24** is located at a patient site, typically the patient's home. In the preferred embodiment, server **12** is a world wide web server, multi-media processor **24** is a web TV processor for accessing the simulation program on server **12**, and links **48** and **50** are Internet links. Specific techniques for establishing client/server computer systems in this manner are well known in the art.

Healthcare provider computer **14** includes a processor and memory, a standard display **16**, and a keyboard **20**. Computer **14** further includes a card slot **18** for receiving a data storage card, such as a smart card **22**. Computer **14** is designed to read data from card **22** and write data to card **22**. Patient multi-media processor **24** includes a corresponding card slot **26** for receiving card **22**. Processor **24** is designed to read data from card **22** and write data to card **22**. Thus, healthcare provider computer **14** communicates with patient multi-media processor **24** via smart card **22**. Such smart card data communication systems are also well known in the art.

Multi-media processor **24** is connected to a display unit **28**, such as a television, by a standard connection cord **32**. Display unit **28** has a screen **30** for displaying simulations to the patient. An input device **34**, preferably a conventional hand-held remote control unit or keyboard, is in signal communication with processor **24**. Device **34** has buttons or keys **36** for entering data in processor **24**.

System **10** also includes an electronic recording device **38** for recording actual control parameter values and patient self-care data indicating actual self-care actions performed by the patient. Recording device **38** includes a measuring device **40** for producing measurements of the disease control parameter, a keypad **44** for entering the self-care data, and a display **42** for displaying the control parameter values and self-care data to the patient.

Recording device **38** is preferably portable so that the patient may carry device **38** and enter the self-care data at regular monitoring intervals. Device **38** is further connectable to healthcare provider computer **14** via a standard connection cord **46** so that the control parameter values and patient self-care data may be uploaded from device **38** to computer **14**. Such recording devices for producing measurements of a disease control parameter and for recording self-care data are well known in the art. For example, U.S. Patent 5,019,974 issued to Beckers on May 28, 1991 discloses such a recording device.

In the example of the preferred embodiment, the disease control parameter is the patient's blood glucose level and recording device **38** is a blood glucose meter, as shown in FIG. 10. In this embodiment, measuring device **40** is a blood glucose test strip designed to test blood received from a patient's finger **54**. Device **38** is also designed to record values of the patient's diet, medications, and exercise durations entered by the patient through keypad **44**. Of course, in alternative embodiments, the recording device may be a peak flow meter for recording a peak flow rate, a cholesterol meter for recording a cholesterol level, etc.

The simulation system of the present invention includes a simulation program which uses a mathematical model to

calculate disease control parameter values. The following variables used in the mathematical model are defined as follows:

N = Normal time interval in which patient self-care actions are employed to make a measurable difference in the disease control parameter or a natural rhythm occurs in the disease control parameter. For diabetes and asthma, time interval **N** is preferably twenty-four hours. For obesity or coronary artery disease, time interval **N** is typically three to seven days.

t_1, t_2,...t_i, t_j...t_N = Time points at which the disease control parameter is measured by a patient. For a daily rhythm control parameter such as a blood glucose level, the time points are preferably before and after meals. For weight or cholesterol control parameters, the time points are preferably once a day or once every second day.

X(t) = Simulated disease control parameter value at time t determined by the simulation program.

R(t) = Optimal control parameter value at time t expected as a normal rhythm value of the disease control parameter at time t if the patient performs optimal self-care actions in perfect compliance from time t_1 to the time point immediately preceding time t.

A(t) = actual control parameter value at time t measured by the patient.

$O_M(t_i)$ = Optimal self-care parameter values $O_1(t_i)$, $O_2(t_i)$, ...$O_m(t_i)$ at time t_i expected to produce optimal control parameter value $R(t_j)$ at time t_j. For

example, a diabetes patient's optimal self-care parameter values include a prescribed dose of insulin, a prescribed intake of carbohydrates, and a prescribed exercise duration.

$S_M(t_i)$ = Patient self-care parameter values $S_1(t_i)$, $S_2(t_i)$, ...$S_m(t_i)$ at time t_i entered in the simulation system by the patient to simulate self-care actions.

$C_M(t_i)$ = Actual self-care parameter values $C_1(t_i)$, $C_2(t_i)$, ...$C_m(t_i)$ at time t_i indicating actual self-care actions performed by the patient at time t_i.

K_M = Corresponding scaling factors $K_1(t_i)$, $K_2(t_i)$, ...K_m for weighting the impact on a future disease control parameter value $X(t_j)$ at time t_j which results from differentials between patient self-care values $S_M(t_i)$ and corresponding optimal self-care values $O_M(t_i)$.

With these definitions, future disease control parameter value $X(t_j)$ is calculated according to the equation:

$$X(t_j) = R(t_j) + (X(t_i) - R(t_i)) + \sum_M K_M(S_M(t_i) - O_M(t_i)).$$

Future disease control parameter value $X(t_j)$ at time t_j is determined from a prior disease control parameter value $X(t_i)$ at time t_i based on an optimal control parameter value $R(t_j)$ at time t_j, the difference between prior disease control parameter value $X(t_i)$ and an optimal control parameter value $R(t_i)$ at time t_i, and a set of differentials between patient self-care values $S_M(t_i)$ and optimal self-care values $O_M(t_i)$. The differentials are multiplied by corresponding scaling factors K_M.

Thus, as patient self-care parameter values $S_M(t_i)$ deviate from optimal self-care parameter values $O_M(t_i)$, future disease control parameter value $X(t_j)$ deviates from optimal control parameter value $R(t_j)$ by an amount proportional to scaling factors K_M. This mathematical model follows the patient's own intuition and understanding that if the patient performs optimal self-care actions in perfect compliance, the patient will achieve the optimal control parameter value at the next measurement time. However, if the patient deviates from the optimal self-care actions, the disease control parameter value will deviate from the optimal value at the next measurement time.

The simulation program is also designed to generate an entry screen for entry of the patient self-care parameter values. FIG. 3 shows a sample patient self-care parameters entry screen **52** as it appears on display unit **28**. The patient self-care parameters include a food exchange parameter expressed in grams of carbohydrates consumed, an insulin dose parameter expressed in units of insulin injected, and an exercise duration parameter expressed in fifteen minute units of exercise performed.

These self-care parameters are illustrative of the preferred embodiment and are not intended to limit the scope of the invention. It is obvious that many different self-care parameters may be used in alternative embodiments. Screen **52** contains data fields **53** for entering a food exchange parameter value $S_1(t)$, an insulin dose parameter value $S_2(t)$, and an exercise duration parameter value $S_3(t)$. Each data field **53** has a corresponding time field **51** for entering a time point corresponding to the patient self-care parameter value. Screen **52** also includes an OK button **55** and a cancel button **57** for confirming and canceling, respectively, the values entered in screen **52**.

FIG. 4 shows a sample table of values **56** created by the simulation program using the data entered by the patient through the self-care parameters entry screen. Table **56** includes a column of simulated disease control parameter values calculated by the simulation program, as will be explained in the operation section below. The simulation program is further designed to generate graphs of simulated disease control parameter values. FIG. 5 illustrates a sample graph **58** generated from table **56** as it appears on screen **30** of the display unit. Specific techniques for writing a simulation program to produce such a graph are well known in the art.

In the preferred embodiment, healthcare provider computer **14** is programmed to determine scaling factors K_M from values of physiological parameters of the patient. FIG. 2 shows a sample physiological parameter entry screen **41** as it appears on the healthcare provider computer. The physiological parameters of the patient include a body mass, a metabolism rate, a fitness level, and hepatic and peripheral insulin sensitivities. These physiological parameters are illustrative of the preferred embodiment and are not intended to limit the scope of the invention. It is obvious that many different physiological parameters may be used in alternative embodiments. Screen **41** includes data fields **43** for entering physiological parameter values, an OK button **45** for confirming the values, and a cancel button **47** for canceling the values.

Healthcare provider computer **14** stores indexes for determining the scaling factors from the physiological parameters entered. For example, FIG. 4 shows an insulin sensitivity scaling factor K_2 corresponding to insulin dose parameter value $S_2(t)$. Computer **14** is programmed to

determine from a stored insulin index a value of scaling factor K_2 based on the entered values of the patient's body mass and insulin sensitivities. In this example, computer **14** determines a value of -40 for scaling factor K_2, indicating that for this patient, one unit of insulin is expected to lower the patient's blood glucose level by 40 mg/dL. Computer **14** is programmed to determine the remaining scaling factors in a similar manner. The specific indexes required to determine the scaling factors from values of a patient's physiological parameters are well known in the art.

In the preferred embodiment, healthcare provider computer **14** is also programmed to adjust scaling factors K_M based on the difference between an actual control parameter value $A(t_j)$ measured at time t_j and optimal control parameter value $R(t_j)$, the difference between an actual control parameter value $A(t_i)$ measured at time t_i and optimal control parameter value $R(t_i)$, and the difference between actual self-care values $C_M(t_i)$ performed by the patient at time t_i and optimal self-care values $O_M(t_i)$.

Scaling factors K_M are adjusted to fit the mathematical model presented above, preferably using a least squares, chi-squares, or similar regressive fitting technique. Specific techniques for adjusting coefficients in a mathematical model are well known in the art. For example, a discussion of these techniques is found in "Numerical Recipes in C: The Art of Scientific Computing", Cambridge University Press, 1988.

The operation of the preferred embodiment is illustrated in FIG. 13. FIG. 13 is a flow chart illustrating a preferred method of using system **10** to simulate the disease control parameter. In step **200**, optimal self-care values and optimal control parameter values for each time point are determined for the patient, preferably by the patient's healthcare

provider. The optimal self-care values and optimal control parameter values are then entered and stored in provider computer **14**.

In the preferred embodiment, the optimal self-care values include an optimal food exchange parameter value $O_1(t)$ expressed in grams of carbohydrates, an optimal insulin dose parameter value $O_2(t)$ expressed in units of insulin, and an optimal exercise duration parameter value $O_3(t)$ expressed in fifteen minute units of exercise. Specific techniques for prescribing optimal self-care values and optimal control parameter values for a patient are well known in the medical field.

In step **202**, the healthcare provider determines the physiological parameter values of the patient and enters the physiological parameter values in computer **14** through entry screen **41**. As shown in FIG. 2, the physiological parameter values include a body mass, a metabolism rate, a fitness level, and hepatic and peripheral insulin sensitivities. Specific techniques for testing a patient to determine these physiological parameter values are also well known in the medical field.

Following entry of the physiological parameter values, computer **14** determines scaling factors K_M from the stored indexes, step **204**. For example, FIG. 4 shows a food exchange scaling factor K_1 corresponding to food exchange parameter value $S_1(t)$, an insulin sensitivity scaling factor K_2 corresponding to insulin dose parameter value $S_2(t)$, and an exercise duration scaling factor K_3 corresponding to exercise duration parameter value $S_3(t)$.

In this example, computer **14** determines a value of 4 for scaling factor K_1, a value of -40 for scaling factor K_2, and

a value of -5 for scaling factor K_3. These values indicate that one gram of carbohydrate is expected to raise the patient's blood glucose level by 4 mg/dL, one unit of insulin is expected to lower the patient's blood glucose level by 40 mg/dL, and fifteen minutes of exercise is expected to lower the patient's blood glucose level by 5 mg/dL. Of course, these values are just examples of possible scaling factors for one particular patient. The values of the scaling factors vary between patients in dependence upon the physiological parameter values determined for the patient.

The determined optimal self-care values, optimal control parameter values, and scaling factors are then stored on smart card **22**, step **206**. Typically, the values are stored on smart card **22** during a patient visit to the healthcare provider. The patient then takes home smart card **22** and inserts smart card **22** in patient multi-media processor **24**, step **208**. Next, the patient accesses the simulation program on server **12** through multi-media processor **24**, step **210**.

The simulation program generates self-care parameters entry screen **52**, which is displayed to the patient on screen **30** of display unit **28**. In step **212**, the patient enters patient self-care values $S_M(t)$ and corresponding time points in data fields **53** and **51**, respectively, using input device **34**. The optimal self-care values, optimal control parameter values, scaling factors, and patient self-care values are transmitted from multi-media processor **24** to server **12** through link **50**. In step **214**, the simulation program calculates simulated disease control parameter values at each time point according to the equation:

$$X(t_j) = R(t_j) + (X(t_i)-R(t_i)) + \sum_M K_M(S_M(t_i)-O_M(t_i))$$

Thus, each future disease control parameter value $X(t_j)$ is calculated from optimal control parameter value $R(t_j)$, the difference between prior disease control parameter value $X(t_i)$ and optimal control parameter value $R(t_i)$, and the set of differentials between patient self-care values $S_M(t_i)$ and optimal self-care values $O_M(t_i)$. The differentials are multiplied by corresponding scaling factors K_M. In the preferred embodiment, first simulated disease control parameter value $X(t_1)$ at time t_1 is set equal to first optimal control parameter value $R(t_1)$ at time t_1. In an alternative embodiment, first simulated disease control parameter value $X(t_1)$ is determined from the last disease control parameter value calculated in a prior simulation.

FIGS. 4 - 5 illustrate a first example of simulated disease control parameter values calculated by the simulation program. Referring to FIG. 4, the simulation program creates table of values **56** having a time column, an optimal control parameter value column, a simulated control parameter value column, three self-care value differential columns indicating differentials between patient self-care parameter values and optimal self-care parameter values, and three corresponding scaling factor columns for weighting the corresponding self-care value differentials.

Table **56** illustrates the simplest simulation, in which the patient follows the optimal self-care actions in perfect compliance at each time point. In this simulation, each patient self-care parameter value equals its corresponding optimal self-care parameter value, so that the simulated disease control parameter value at each time point is simply equal to the optimal control parameter value at each time point. Referring to FIG. 5, the simulation program generates graph **58** of the simulated disease control parameter values.

Graph **58** is displayed to the patient on screen **30** of display unit **28**, step **216**.

FIGS. 6 - 7 illustrate a second example of simulated disease control parameter values calculated by the simulation program. FIG. 6 shows a table of values **59** having identical structure to table **56**. Table **59** illustrates a simulation in which the patient consumes 10 extra grams of carbohydrates at 8:00 and exercises for 60 extra minutes at 15:00. In this simulation, the differential $S_1(t) - O_1(t)$ is equal to 10 at 8:00 due to the 10 extra grams of carbohydrates consumed by the patient. Because scaling factor K_1 equals 4, the simulation program calculates simulated disease control parameter value $X(t_2)$ at time point 10:00 as 40 mg/dL higher than optimal control parameter value $R(t_2)$ at 10:00.

Similarly, the differential $S_3(t) - O_3(t)$ is equal to 4 at time point 15:00 due to the 60 extra minutes of exercise performed by the patient. With simulated disease control parameter value $X(t_4)$ exceeding optimal control parameter value $R(t_4)$ by 40 mg/dL at 15:00 and with scaling factor K_3 equal to -5, the simulation program calculates simulated disease control parameter value $X(t_5)$ at time point 18:00 as 20 mg/dL higher than optimal control parameter value $R(t_5)$. FIG. 7 shows a graph **60** of the simulated disease control parameter values determined in table **59**. Graph **60** is displayed to the patient on screen **30** of the display unit.

FIGS. 8 - 9 illustrate a third example of simulated disease control parameter values calculated by the simulation program. Referring to FIG. 8, a table of values **61** illustrates a simulation in which the patient consumes 10 extra grams of carbohydrates at 8:00, injects 1 extra unit of insulin at 10:00, and exercises for 60 extra minutes at 15:00. The differential $S_2(t) - O_2(t)$ is equal to 1 at

10:00 due to the 1 extra unit of insulin injected by the patient. With simulated disease control parameter value $\mathbf{X(t_2)}$ exceeding optimal control parameter value $\mathbf{R(t_2)}$ by 40 mg/dL at 10:00, and with scaling factor $\mathbf{K_2}$ equal to -40, the simulation program calculates simulated disease control parameter value $\mathbf{X(t_3)}$ at time point 12:00 as equal to optimal control parameter value $\mathbf{R(t_3)}$. FIG. 8 shows a graph **62** of the simulated disease control parameter values determined in table **61**.

In addition to performing simulations with the simulation program, the patient records actual control parameter values and actual self-care values indicating actual self-care actions performed by the patient at each time point, step **218**. These values are preferably recorded in recording device **38**. Upon the patient's next visit to the healthcare provider, the actual control parameter values and actual self-care values are uploaded to provider computer **14**, step **220**. Those skilled in the art will appreciate that recording device **38** may also be networked to provider computer **14** through a modem and telephone lines or similar network connection. In this alternative embodiment, the actual control parameter values and actual self-care values are transmitted directly from the patient's home to provider computer **14**.

In step **222**, provider computer **14** adjusts scaling factors $\mathbf{K_M}$ based on the difference between the actual control parameter values and the optimal control parameter values at each time point and the difference between the actual self-care values and the optimal self-care values at each time point. Scaling factors $\mathbf{K_M}$ are adjusted to fit them to the actual patient data recorded. In this manner, the scaling factors are customized to the individual patient to enable the patient to run customized simulations. The new values of the scaling

factors are stored on smart card **22** which the patient takes home and inserts in processor **24** to run new simulations.

FIGS. 11 - 12 illustrate a second embodiment of the invention. The second embodiment differs from the preferred embodiment in that the components of the simulation system are contained in a single stand-alone computing device **64**. The second embodiment also differs from the preferred embodiment in that the system predicts each future disease control parameter value from an actual measured disease control parameter value rather than from a prior simulated disease control parameter value.

Referring to FIG 11, computing device **64** includes a housing **66** for holding the components of device **64**. Housing **66** is sufficiently compact to enable device **64** to be hand-held and carried by a patient. Device **64** also includes measuring device **40** for producing measurements of actual control parameters values and a display **70** for displaying data to the patient. Device **64** further includes a keypad **68** for entering in device **64** the optimal control parameter values, the optimal self-care values, the patient self-care parameter values, the actual self-care parameter values, and the patient's physiological parameter values.

FIG. 12 shows a schematic block diagram of the components of device **64** and their interconnections. Device **64** has a microprocessor **72** and a memory **74** operably connected to microprocessor **72**. Measuring device **40** and display **70** are also connected to microprocessor **72**. Keypad **68** is connected to microprocessor **72** through a standard keypad decoder **78**. Microprocessor **72** is connected to an input/output port **76** for entering in device **64** a simulation program to be executed by microprocessor **72** which will be explained in detail below.

Memory **74** stores the optimal control parameter values, the optimal self-care values, the patient self-care parameter values, the actual self-care parameter values $C_M(t)$, the scaling factors, and the patient's physiological parameter values. Memory **74** also stores the simulation program to be executed by microprocessor **72** and the indexes for calculating the scaling factors from the patient's physiological parameter values.

In the second embodiment, microprocessor **72** is programmed to perform the functions performed by the healthcare provider computer of the preferred embodiment. The functions include determining scaling factors K_M from the patient's physiological parameter values. The functions also include adjusting scaling factors K_M based on the difference between actual control parameter value $A(t_j)$ and optimal control parameter value $R(t_j)$, the difference between actual control parameter value $A(t_i)$ and optimal control parameter value $R(t_i)$, and the difference between actual self-care values $C_M(t_i)$ and optimal self-care values $O_M(t_i)$.

The operation of the second embodiment is shown in FIG. 14. FIG. 14 is a flow chart illustrating a preferred method of using the system of the second embodiment to predict an effect of patient self-care actions on a disease control parameter. In step **300**, the optimal control parameter values and optimal self-care values are entered in device **64** and stored in memory **74**. The optimal control parameter values and optimal self-care values may be entered in device **64** either through keypad **68** or through input/output port **76**.

In step **302**, the patient or healthcare provider determines the patient's physiological parameter values. The physiological parameter values are then entered in device **64** through keypad **68** and stored in memory **74**. Following entry

of the physiological parameter values, microprocessor **72** determines scaling factors K_M from the indexes stored in memory **74**, step **304**. Scaling factors K_M are then stored in memory **74**. In an alternative method of determining and storing scaling factors K_M in memory **74**, scaling factors K_M are determined in a healthcare provider computer, as previously described in the preferred embodiment. Scaling factors K_M are then entered in device **64** through keypad **68** or port **76** and stored in memory **74**.

In step **306**, the patient enters in microprocessor **72** actual disease control parameter $\mathbf{A(t_i)}$. To enter actual disease control parameter $\mathbf{A(t_i)}$, the patient places his or her finger on measurement device **40** at time t_i. Measurement device **40** produces a measurement of actual disease control parameter $\mathbf{A(t_i)}$ which is stored in memory **74**. In step **308**, the patient enters in microprocessor **72** patient self-care values $\mathbf{S_M(t_i)}$ using keypad **68**. In step **310**, microprocessor **72** executes the simulation program stored in memory **74** to calculate future disease control parameter value $\mathbf{X(t_j)}$.

The simulation program of the second embodiment differs from the simulation program of the preferred embodiment in that future disease control parameter value $\mathbf{X(t_j)}$ is calculated from actual disease control parameter $\mathbf{A(t_i)}$ rather than from a prior simulated disease control parameter value. In the second embodiment, future disease control parameter value $\mathbf{X(t_j)}$ is calculated according to the equation:

$$X(t_j) = R(t_j) + (A(t_i) - R(t_i)) + \sum_M K_M(S_M(t_i) - O_M(t_i))$$

Thus, future disease control parameter value $\mathbf{X(t_j)}$ is determined from optimal control parameter value $\mathbf{R(t_j)}$, the difference between actual disease control parameter $\mathbf{A(t_i)}$ and optimal control parameter value $\mathbf{R(t_i)}$, and the set of

differentials between patient self-care values $S_M(t_i)$ and optimal self-care values $O_M(t_i)$. The differentials are multiplied by corresponding scaling factors K_M. Future disease control parameter value $X(t_j)$ is displayed to the patient on display **70**, step **312**.

Once future disease control parameter value $X(t_j)$ is displayed to the patient, the patient uses the value to select appropriate actual self-care actions to perform at time t_i. Alternatively, the patient may perform several more simulations of future disease control parameter value $X(t_j)$ to decide appropriate self-care actions to perform at time t_i. Once the patient has performed the self-care actions, the patient enters in microprocessor **72** actual self-care values $C_M(t_i)$ indicating the self-care actions performed, step **314**. The actual self-care values are then stored in memory **74**.

The patient also enters in microprocessor **72** actual disease control parameter $A(t_j)$ measured at time t_j. To enter actual disease control parameter $A(t_j)$, the patient places his or her finger on measurement device **40** at time t_j. Measurement device **40** produces a measurement of actual disease control parameter $A(t_j)$ which is stored in memory **74**, step **316**. In step **318**, microprocessor **72** adjusts scaling factors K_M based on the difference between actual control parameter value $A(t_j)$ and optimal control parameter value $R(t_j)$, the difference between actual control parameter value $A(t_i)$ and optimal control parameter value $R(t_i)$, and the difference between actual self-care values $C_M(t_i)$ and optimal self-care values $O_M(t_i)$. In this manner, the scaling factors are customized to the individual patient to enable the patient to run customized simulations. The new values of the scaling factors are stored in memory **74** and used by microprocessor **72** in subsequent simulations.

SUMMARY, RAMIFICATIONS, AND SCOPE

Although the above description contains many specificities, these should not be construed as limitations on the scope of the invention but merely as illustrations of some of the presently preferred embodiments. Many other embodiments of the invention are possible. For example, the preferred embodiment is described in relation to diabetes. However, it is obvious that the system and method of the invention may be used for simulating any disease which has a measurable control parameter and which requires patient self-care actions. Similarly, the self-care parameters, corresponding scaling factors, and physiological parameters described are exemplary of just one possible embodiment. Many different self-care parameters, scaling factors, and physiological parameters may be used in alternative embodiments.

The preferred embodiment also presents a simulation system that includes a server, a healthcare provider computer, and patient multi-media processor communicating with the provider computer via a smart card. This configuration of system components is presently preferred for ease of setting, storing, and adjusting the model parameters and scaling factors under the supervision of a healthcare provider. However, those skilled in the art will recognize that many other system configurations are possible. For example, in one alternative embodiment, the system is configured as a single stand-alone computing device for executing simulations.

In another embodiment, the smart card is eliminated from the simulation system. In this embodiment, the model parameter values and scaling factors are transmitted directly to the server from the healthcare provider computer. In a further

embodiment, the provider computer is also eliminated and the recording device is networked directly to the server. In this embodiment, the server is programmed to set, store, and adjust the model parameters and scaling factors based on patient data received through the recording device and patient multi-media processor.

In yet another embodiment, the server is eliminated and the simulation program is run on the patient multi-media processor. In this embodiment, the recording device and multi-media processor may also be networked directly to the provider computer, eliminating the need for a smart card. Specific techniques for networking computers and recording devices in these alternative system configurations are well known in the art.

Further, the first embodiment is described as a system for simulating a disease control parameter from simulated data and the second embodiment is described as a system for predicting a future value of a disease control parameter from actual patient data. These systems are presented in separate embodiments for clarity of illustration and ease of understanding. However, it is anticipated that both embodiments could be combined into a single simulation system for simulating disease control parameter values from simulated data, actual patient data, or a combination of simulated and actual data.

Therefore, the scope of the invention should be determined not by the examples given but by the appended claims and their legal equivalents.